K102035

510(k) Summary

DEC 1 2010

Applicant Information

Date Prepared: September 8th 2010

Submitter: ClearStream Technologies Ltd

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Device Information

Trade Name: Sleek OTW PTA Catheter

Common Name: OTW PTA Catheter

Classification Name: Percutaneous Catheter

Classification: Class II, 21 CFR 870.1250

Product Code: LIT

Predicate Device:

ClearStream Technologies Ltd, proposes its **Bantam α PTA Catheter** cleared through the following 510(k) number submission: **K093139**, as the predicate device for this submission.

Device Description:

The Sleek OTW PTA Catheter is a standard over-the-wire PTA catheter. The co-axial catheter has a balloon located near the distal tip. One lumen is used for inflation of the balloon, while the internal lumen allows access to the distal

tip of the catheter for guidewire insertion (0.014"). The balloon expands to a known diameter at specific pressure.

Raw Materials

Materials	Usage
Pebax	Bridge tubing
Co-extruded Nylon/Pebax	Shaft Inner Material
Blue colorant	Colorant for Inner tube
Nylon/ Pebax blend	Balloon tubing
Platinum / Iridium band	Marker band
Nylon / Pebax Blend Nylon blend	Shaft Outer Material: 1.25mm & 1.5mmx15mm 1.5mmx20mm – 5.0mmx120mm
Loctite	Hub bond.glue
Pebax	Strain Relief
Polycarbonate	Y- Connector
Polycarbonate	Luer hub
Nylon/Pebax Blend	Reinforcement Material
Teflon	Balloon Sleeve
Stainless steel	Flexible Shipping mandrel
Domino Amjet Ink	Print on hub and strain relief
Silicon	SiLX coating
HDPE	Hoop
Polyester / Polyethylene / Tyvek	Pouch

The Product Specifications of the Sleek OTW PTA Catheter is as follows:

Balloon	
Nominal pressure	6Atm
Rated burst pressure 1.25mm and 1.5mm by 15 mm	14Atm
Rated burst pressure 1.5mm by 20 – 220mm	16Atm
Rated burst pressure 2.0 – 4.0mm by 20-40mm	16Atm
Rated burst pressure 5.0mm by 20-60mm	14Atm
Rated burst pressure 2.0 – 4.0mm by 80 - 220mm	15Atm
Rated burst pressure 5.0mm by 80 - 220mm	13Atm
Average burst pressure 1.25mm by 15 mm	23Atm
Average burst pressure 1.5mm by 15 mm	21Atm
Average burst pressure 1.5mm by 20 - 220mm	22Atm
Average burst pressure 2.0 – 4.0mm by 20 - 40mm	22Atm
Average burst pressure 5.0mm by 20 - 40mm	20Atm
Average burst pressure 2.0 – 4.0mm by 80 - 220mm	21Atm
Average burst pressure 5.0mm by 80 - 220mm	19Atm
Average compliance 1.25mm and 1.50mm	10% ± 4%
Average compliance	8% ± 4%
Deflation time	< 45 Secs
Fold	Trifold with memory for 2.5 – 5.0mm, bifold for 1.25 - 2.0mm
Tip lead in profile	<0.018" – 0.021" sliding scale by balloon diameter
Sheath Compatibility 1.5mm – 5.0mm	4F
Shaft	
Overall catheter length	100, 130 and 150cm
Shaft Format	Co-axial
Guidewire Max. wire diameter	0.014"
Shaft Outer Diameter	2.5F/3.2F (1.25 and 1.5) 2.8F/3.6F (other sizes)
Hub	Polycarbonate with dual standard luer fittings
Marker Bands	Platinum marker bands

Catalogue number of the Sleek OTW

Catheter Length 100cm	Balloon Lengths (mm)						
Inflated Balloon Diameter	20	40	80	100	120	150	220
1.5	426-1502L	426-1504L	426-1508L	426-1510L	426-1512L	-	-
2.0	-	426-2004L	426-2008L	426-2010L	426-2012L	426-2015L	426-2022L
2.5	-	426-2504L	426-2508L	426-2510L	426-2512L	426-2515L	426-2522L
3.0	-	426-3004L	426-3008L	426-3010L	426-3012L	426-3015L	426-3022L
3.5	-	426-3504L	426-3508L	426-3510L	426-3512L	-	-
4.0	-	426-4004L	426-4008L	426-4010L	426-4012L	-	-
5.0	-	426-5004L	426-5008L	426-5010L	426-5012L	-	-

Catheter Length 130cm	Balloon Lengths (mm)						
Inflated Balloon Diameter	20	40	80	100	120	150	220
1.5	426-1502W	426-1504W	426-1508W	426-1510W	426-1512W	-	-
2.0	-	426-2004W	426-2008W	426-2010W	426-2012W	426-2015W	426-2022W
2.5	-	426-2504W	426-2508W	426-2510W	426-2512W	426-2515W	426-2522W
3.0	-	426-3004W	426-3008W	426-3010W	426-3012W	426-3015W	426-3022W
3.5	-	426-3504W	426-3508W	426-3510W	426-3512W	-	-
4.0	-	426-4004W	426-4008W	426-4010W	426-4012W	-	-
5.0	-	426-5004W	426-5008W	426-5010W	426-5012W	-	-

Catheter Length 150cm	Balloon Lengths (mm)							
Inflated Balloon Diameter	15	20	40	80	100	120	150	220
1.25	426-1201X	-	-	-	-	-	-	-
1.5	426-1501X	426-1502X	426-1504X	426-1508X	426-1510X	426-1512X	-	-
2.0	-	-	426-2004X	426-2008X	426-2010X	426-2012X	426-2015X	426-2022X
2.5	-	-	426-2504X	426-2508X	426-2510X	426-2512X	426-2515X	426-2522X
3.0	-	-	426-3004X	426-3008X	426-3010X	426-3012X	426-3015X	426-3022X
3.5	-	-	426-3504X	426-3508X	426-3510X	426-3512X	-	-
4.0	-	-	426-4004X	426-4008X	426-4010X	426-4012X	-	-
5.0	-	-	426-5004X	426-5008X	426-5010X	426-5012X	-	-

Intended Use:

Balloon dilatation of the femoral, popliteal and infra-popliteal arteries. These catheters are not designed to be used in the coronary arteries.

Comparison to Predicate Device:

The Bantam α product FDA approved under K093139 is the same as the Sleek OTW product in all aspects including material, composition and processing except for the addition of a bridge tubing located in the distal tip of the Sleek OTW product. A list of aspects of the product that are the same is shown below:

as supplied in materials table above

Part	**Bantam α FDA approved**	**Sleek**
Hub	Same	Same
Strain relief	Same	Same
Outer	Same Same	Same
Inner	Same	Same
Balloon	Same	Same
Marker bands	Same	Same

Bridge material	NA	Pebax
Re-inforcement	Same	Same
		Same
Bonds		Same
Hub	Glued (inner and outer into hub)	Same
Proximal bond	Fused (Outer to balloon)	Same
Marker bands	Crimped (bands to inner)	Same
Distal bond	Fused (inner to balloon + additional pebax)	Same

Details of the bridging material are laid out below:

- The addition of a bridge material, the same as that used in the LitePAC (K100490) (Sleek - K072947) design.
- The distal end configuration of Sleek OTW differs slightly to that of Bantam α, with a tip lead in profile of: 0.018" for a 1.25mm balloon diameter and 0.021" for a 5.0mm balloon diameter for Sleek OTW; while the tip lead in profile for Bantam α is 0.017" for a 1.25mm balloon and up to 0.020" for a 5.0mm balloon.

The only extra testing deemed necessary for Sleek OTW was testing relating to the distal tip due to the bridge tubing addition. All testing of the distal tip passed specification. All testing was done in compliance with ISO 10555-1 and ISO 10555-4 requirements. Due to the minor nature of the change and the fact that all subsequent testing on the Sleek passed requirements the products are deemed substantially equivalent.

Test Data:

The safety and effectiveness of the ClearStream Sleek OTW PTA Catheter has been demonstrated through data collected from non-clinical design verification and design validation tests and analyses.

Bench Testing

The Sleek OTW bench testing validations consist of the same and additional tests as the previous Bantam α validation. All validation work for the Sleek OTW originally focused specifically around the distal tip change as this was the only difference between the two products, however after a customer request this validation was extended to cover a wider range of tests.

The Sleek OTW product is identical to the currently CE marked and FDA approved Bantam α product (K093139) except for the inclusion of a bridge tubing in the distal tip. Through testing, the distal tip configuration has proven its safety and effectiveness and as such Sleek OTW and Bantam α are deemed to be substantially equivalent despite this addition of the bridge material. As everything up to the tip of the catheter is the same for the Bantam α and the Sleek OTW, further testing would not have provided any further information. Table 1. lays out the testing performed for the Bantam α (please note the Bantam validation was also referenced as part of the Bantam α project due to the same materials and processes being used) and the corresponding testing done for the Sleek OTW is also described.

In addition to the tests carried out in the Bantam α validation, some additional tests were carried out in the Sleek OTW validations described in Table 2 below. These extra validation tests for Sleek OTW were carried out due to a customer request.

A full functional validation of Sleek OTW, VP577, was carried out at the customer's request. The tests, "Catheter Body Dimensions" and "Visual and Functional test" from the functional validation of Bantam α, VP494, were not carried out. The catheter body

dimension test was not required as the dimensions of the two products are the same up to the distal tip. Visual and functional testing was performed on the line for the Sleek OTW product as part of routine production and so it was not necessary to be performed again as part of the validation.

Table 1

Test	Results Bantam α (VP/VR494) & Bantam (VP/VR421,338 & 222)	Results Sleek OTW (VP/VR577)
Visual and Functional Testing	PASS – VP494 [29 of 1.5x20x150], [29 of 5.0x120x150] Also completed on VP421 - Pass (13 of 2.0x220), (13 of 2.5x220) (13 of 5.0x220), (42 of 6.0x220)	N/A
Catheter Body Diameters	PASS – VP494 [29 of 1.5x20x150], [29 of 5.0x120x150] Also completed on VP421 – Pass (13 of 2.0x220), (13 of 2.5x220) (13 of 5.0x220), (29 of 6.0x220)	N/A
Test	**Results Bantam α (VP/VR494) & Bantam**	**Results Sleek OTW (VP/VR577)**

	(VP/VR421,338 & 222)	
	PASS – VP494 [29 of 5x120mmx150cm] Also completed on VP421 – Pass (13 of 2.5x220) (13 of 5.0x220) (29 of 6.0x220)	N/A
Inflation/Deflation Time	N/A	PASS - VP577 [29 of 5x120mmx150cm]
Introducer Sheath Withdrawal	PASS [29 of 5x120mmx150cm] VP421 – Pass (13 of 5.0x220), (29 of 6.0x220)	PASS [29 of 5x120mmx150cm]
Leak and Rated Burst Pressure	PASS [29 of 1.5x20mmx150cm] [29 of 5x120mmx150cm] VP421 – Pass (13 of 2.5x220), (13 of 5.0x220) (29 of 6.0x220)	*PASS with deviation [29 of 1.25x15mmx150cm] [29 of 5x120mmx150cm]
Test	**Results Bantam α (VP/VR494) & Bantam (VP/VR421,338 & 222)**	**Results Sleek OTW (VP/VR577)**
Tensile Test for	VP/VR 338 – Pass	PASS

Proximal Bond	(29 of 2x20 Pass) (29 of 2x120 Pass) (13 of 5x120 Pass) (29+13 of 9x60 Pass)	[29 of 5x120mmx150cm]
Tensile Test for Hub Bond	VP222 – Pass (29 of 2x60), (29 of 3x60) (29 of 5x60), (29 of 6x60) (29 of 8x60), (29 of 9x60)	PASS [29 of 5x120mmx150cm]
Measurement of the Working Surface, OD and TL of the Balloon	VP 421 - Pass (13 2.0x220)	PASS [13 of 1.25x15mmx150cm] [13 of 5x120mmx150cm]
Balloon Compliance Test	VP 421 – Pass (13 2.0x220) (13 6.0x220)	PASS [13 of 1.25x15mmx150cm] [16 of 5x120mmx150cm]
Average Burst Pressure Testing	VP 421 – Pass (13 2.0x220) (13 6.0x220)	PASS [13 of 1.25x15mmx150cm] [13 of 5x120mmx150cm]

Conclusion: All products had acceptable balloon fatigue performance, noted deviation accepted.

The additional tests carried out for Sleek OTW are detailed in Table 2 below:

Table 2

Test	Results Sleek OTW (VP/VR577)
Profile Measurements of Distal Tip	PASS – VP577 [29 of 1.25x15x150], [29 of 5.0x120x150]
Tensile Test of the Distal Tip	PASS [29 of 1.25x15mmx150cm] [29 of 5x120mmx150cm]

Conclusions

ClearStream Technologies Ltd believes that the data and information presented in this application, including in vitro testing and numerous device similarities support a determination of substantial equivalence, making the device as safe and effective and therefore market clearance of the Sleek OTW catheter through this 510(k) premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ClearStream Technologies Ltd.
C/O Fiona Ni Mhullain
Regulatory Affairs Manager
Moyne Upper
Enniscorthy, Ireland

DEC 1 2010

Re: K102035
Trade/Device Name: Sleek OTW catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: Undated
Received: November 12, 2010

Dear Ms. Mhullain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102035

Device Name: Sleek OTW PTA Catheter

Indications for Use:

Balloon dilatation of the femoral, popliteal and infra-popliteal arteries. These catheters are not designed to be used in the coronary arteries.

Prescription Use		Over-The-Counter Use
___XX___ (Part 21 CFR 801 Subpart D)	AND/OR	_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Bahner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102035